Department of Health Professions

Virginia Board of Pharmacy Law Update

VPhA Annual Meeting
July 30, 2013

Caroline Juran, Executive Director

Current Board Members

- Jody H. Allen, Chairman
- Ellen B. Shinaberry, Vice-Chairman
- David C. Kozera
- R. Crady Adams
- Dinny Li (citizen)
- Empsy Munden
- Robert M. Rhodes
- Pratt P. Stelly (citizen)
- Rebecca Thornbury
- Cynthia Warriner

Program Objectives

- Briefly review new laws impacting pharmacy
- Provide status update of proposed regulations
- Review board guidance for compliance with USP-NF standards for compounding
- Summarize most recently cited inspection deficiencies

New Laws Impacting Pharmacy Resulting from 2013 General Assembly Session

(Effective July 1, 2013)

HB1422 Biosimilars

- Amends §§54.1-3408.04 and 54.1-3401
- Authorizes pharmacist to dispense biosimilars
- Drug must be licensed by FDA as interchangeable
- Pharmacist must inform patient and provide retail cost for both
- Notify prescriber of substitution
- Record brand name or product name and manufacturer on dispensing record and label

HB1499 EMS Administration

- Amends §54.1-3408 B
- Clarifies when EMS may administer meds
  - Oral order
  - Written order
  - Standing protocol
- Proposed exempt regulatory action recognizes standing protocols and eliminates need for administration record to be signed by prescriber
- Proposed that administration record still accompany opened kit to pharmacy

HB1499 EMS Administration

- Exempt regulatory changes not in effect at this time
- Board to consider need for additional regulatory amendments in near future

HB1501 Collaborative Practice

- Amends §§54.1-3300 and 54.1-3300.1
- Clarifies with whom pharmacist may enter into agreement (adds nurse practitioners, PAs, and physician's office)
- Patient must notify prescriber to opt out
- Prescriber may elect for patient to not participate by contacting pharmacist or documenting on prescription

HB1501 Collaborative Practice

- Clarifies agreement may be in writing or electronic
- Authorizes pharmacist to implement drug therapy following diagnosis by prescriber
- Joint BOM and BOP regulations will need amending
- Ad hoc committee meeting – ***August 20, 2013, 9AM***

HB 1672 Naloxone

- Amends §54.1-3408 by adding subsection X
- Within pilot program, allows person to obtain prescription for naloxone to administer to family member or friend
- Counteract opiate overdoses
- Pilot scheduled to be implemented in September
- Richmond area and southwest Virginia
- DBHDS to report back to GA in December 2014

HB 2136 Scheduling

- Amends §54.1-3450
- Adds methasterone and prostanozol (anabolic steroids) to Schedule III
- Conforms law to DEA scheduling

HB 2181 Medical Equipment Suppliers

- Amends §54.1-3435.2
- Authorizes MES to store and distribute sterile water and saline for irrigation

HB 2312 Compounding & Nonresident Pharmacies

- Amends §54.1-2408.1
- Clarifies Board's ability to summarily suspend or restrict a permit when the continued practice constitutes a substantial danger to the public health or safety

HB 2312 Compounding & Nonresident Pharmacies

- Amends §54.1-3401to clarify definition of “compounding”
- Adds H3 to §54.1-3410.2
- Clarifies manufacturing = compounding of inordinate amounts when no observed historical pattern of prescriptions and dispensing

HB 2312 Compounding & Nonresident Pharmacies

- Adds K to §54.1-3410.2
- Every PIC or owner (includes nonresident pharmacies) must notify Board of intent to dispense or deliver compounded sterile drug in VA
- Upon renewal, must notify board of intent to continue
- Requires Board to have ability to produce list of those performing sterile compounding

HB 2312 Compounding & Nonresident Pharmacies

- Amends §54.1-3434.1
- Requires nonresident pharmacies to provide inspection report performed within 6 months of submission of new application and 2 years of renewal application
- Must indicate compliance with USP-NF if compounding
- Guidance Document 110-38 = will accept inspection report from NABP if satisfies requirements

Proposed Regulatory Action

18VAC110-20-355 Automated Counting Devices

- Fast-track regulatory change – ***Effective August 2, 2013***
- Removes requirement to perform run dry every 60 days
- Proposed language states:
  - If recall of a drug added to bin in last three months or if recalled drug known to remain in bin, all drugs shall be removed and not used for patient care

18VAC110-20-355 Automated Counting Devices

- Removal of drugs not required if:
  - technology of device can ensure drugs in a particular lot have been cleared or
  - bin was "run dry," with a record made of the "run dry" date, since addition of recalled lot number
- Device shall be cleaned, maintained in accordance with recommended manufacturer guidelines and specifications

On-hold Prescriptions

- Initiated in 2010
- ***Proposed regulations*** require:
  - Filing of prescription by date of initial dispensing *or date of initial entry into automated data processing system*
  - Documentation that pharmacist verified accuracy of data entry
  - Data entry of on-hold prescription must occur

On-hold Prescriptions

- ***Proposed regulations*** require:
  - Pharmacist dispensing on-hold prescription must perform prospective drug review
  - data entry must be deleted if patient requests on-hold prescription back prior to dispensing
- **Comment period 6/3/13 to 8/2/13**

18VAC110-20-490 Automated dispensing devices

- ***Proposed regulatory*** amendments adopted by Board in June 2012
- Resulted from 3 petitions for rulemaking
- Will eliminate some manual auditing processes if technology used which accomplishes task, and clarifies language
- **Comment period 6/3/13 to 8/2/13**

18VAC110-20-418 Continuous Quality Improvement

- §54.1-3434.03 requires all pharmacies to comply with CQI regulations or report to patient safety organization
- Emergency regulations effective 10/1/2012 to 9/30/2013
- Proposed replacement regulations in Governor's office
- Currently no monetary penalty for non-compliance; Board to revisit in future

Working Conditions

- Petition for rulemaking received in February 2012
- Requests Board to implement rules similar to WV and NC to restrict number of continuous hours a pharmacist may work and require meal breaks
- Board adopted NOIRA in June

Working Conditions

- Awaiting approval to publish the NOIRA
- Currently in the Secretary's office for review
- Additional opportunity for public comment once published

Governor's Regulatory Reform Initiative

- Intended to reduce or remove burdensome regulations
- Fast-track process
- Non-controversial amendments

Governor's Regulatory Reform Initiative

Proposed amendments:

- 18VAC110-20-20- deletes outdated fees
- 18VAC110-20-40- clarifies conditions under which Board may accept hours of practical experience certified by school of pharmacy in another state
- 18VAC110-20-105- deletes requirement for pharmacy technicians to provide "proof" of CE compliance when performing late renewal; simply requires attestation

Governor's Regulatory Reform Initiative

Proposed amendments:

- 18VAC110-20-270- places guidance from Guidance Document 110-22 into regulation to clarify requirements for prescription verification
- 18VAC110-20-420- requires unit dose dispensing drawers to be labeled in a manner to identify the patient and his location without violating health privacy laws

Governor's Regulatory Reform Initiative

Proposed amendments:

- 18VAC110-20-425- expands allowance for hospital and LTC pharmacies to use robotic pharmacy systems that dispense compliance packaging
- 18VAC110-20-710- exempts teaching institutions from alarm requirement when possessing only CVI drugs
- **Comment period 8/12/2013 to 9/11/2013**

Board Guidance for Compliance with USP-NF Standards for Compounding

Compounding

- §54.1-3410.2 requires sterile and non-sterile compounding to comply with USP-NF requirements
- Ad hoc committee on compounding – *May 2013*
- Board amended Guidance Document 110-36 to include 34 FAQs on subject– *June 2013*

Guidance Document 110-36

- Compliance not limited to USP <797>
- USP assigns BUDs for low, medium, high-risk
- CSPs cannot exceed BUDs in absence of sterility testing
- Don’t confuse sterility with stability
- Skip lot testing does not equate to sterility testing
- Certification of hoods and rooms must be performed every 6 months (no later than last day of sixth month)

Guidance Document 110-36

- All compounding personnel must pass media-fill testing prior to performing sterile compounding, annually (12 months) for low and medium-risk, semi-annually (6 months) for high-risk
- Fail media-fill test = no compounding until pass
- Avastin cannot be repackaged for office-use; may repackage and dispense pursuant to patient-specific prescription

Guidance Document 110-36

- Non-sterile compounds should not exceed recommended BUDs in <795> unless pharmacist maintains full documentation justifying appropriateness
- Hazardous CSPs cannot be compounded in same hood as non-hazardous
- Bladder irrigation fluids must be prepared in sterile manner
- Cannot compound drug for prescriber who intends to dispense drug to his patients

Frequently Cited Deficiencies During Routine Pharmacy Inspections

Major Deficiencies Commonly Cited

- **Monthly perpetual inventory of Schedule II**
- Insufficient enclosures or locking devices
- Inadequate alarm coverage or no back-up
- No incoming PIC or biennial inventory
- Refrigerator/freezer temperature out of range
- Unauthorized access to alarm or key to Rx dept
- Storage of drugs not in Rx dept

Major Deficiencies Commonly Cited

- Pharmacists failing to verify or document verification of accuracy of dispensed product
- Last quarter = Media-fill testing; room and hood certifications

Minor Deficiencies Commonly Cited

- Emergency alarm code/key not maintained in compliance
- Inventories taken, but not in compliance
- No documentation for partial-filling
- Expired drugs
- Labels don’t include all required info
- Repackaging and compounding records not complete

Board Adopted Legislative Proposals for 2014 General Assembly Session

Scheduling

- Proposal to place locaserin (new weight loss drug) into Schedule IV
- Conforms with recent DEA scheduling action

Tramadol

- Proposal to place tramadol into Schedule IV
- Not scheduled federally
- 12 states have placed into CIV or “drug of concern”

Physician Selling

- Proposal to authorize Board to license facilities associated with practitioners of the healing arts licensed to sell controlled substances
- Currently difficult for Board to ensure proper oversight given increase in number of dispensing physicians
- Does not expand physician's current authority
- Formalizes existing process

Additional Actions of those Summarily Restricted or Suspended

- Proposal to authorize health regulatory boards to take additional actions of those summarily restricted or suspended
- Including but not limited to drug recalls

Wholesale Distributor Reporting Requirement

- Proposal to require wholesale distributors & nonresident wholesale distributors to:
  - notify Board and Virginia State Police
  - within 5 days of ceasing or restricting distribution to a dispenser
  - due to suspicious ordering

Wholesale Distributor Reporting Requirement

- Description of “suspicious activity” analogous to federal reporting requirements in 21CFR1301.74
- Proposal identified during NGA Policy Grant meetings to reduce prescription drug abuse

Miscellaneous

Prescription Validity

- Prescriptions being received in VA pharmacies from out of state prescriber and patient resides in a third state
- June 2012 Board e-newsletter article
- Use professional judgment, taking “red flags” into consideration

Use the PMP to Assist in Determining Validity of Prescription!!

- Approximately 4,000 pharmacists now registered! (12,000 prescribers)
- PMPi – Interoperability
- Arizona, Colorado, Connecticut, Illinois, Indiana, Kansas, Kentucky, Louisiana, Michigan, New Mexico, North Dakota, Ohio, South Carolina, South Dakota, and Virginia
- Estimate 30 states by end of 2013

Board E-newsletters

- Next publication = first of August
- Published 3-4 times annually
- Provide current email address to Board

Domperidone

- Not FDA-approved
- 2004, FDA warned compounding pharmacies & firms
- FDA import alert on drug shipment
- Potential health threats for lactating women – cardiac arrhythmia, sudden death
- Only available through Expanded Access to Investigational Drugs for severe GI motility disorders refractory to standard therapy

Domperidone

- Certain specified suppliers
- FDA authorization must be obtained prior to the importation, interstate shipment, and administration of the drug
- No pharmacies in VA currently have FDA-approval to compound with domperidone

Domperidone

- Expanded Access to Investigational Drugs
- FDA Division of Drug Information at: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm082585.htm
- Toll free 855-543-3784 or 301-796-3400
- druginfo@fda.hhs.gov

Nurse Practitioners' Prescription Authority Number

- Joint emergency regulations of Boards of Medicine and Nursing effective May 8, 2013 through May 7, 2014
- Nurse practitioner no longer required to include prescriptive authority number on prescription if DEA registration number included
- If no DEA number, must include prescriptive authority number on CVI prescriptions

Purchasing Drugs

- Ensure prescription drugs are purchased only from licensed entities
- Verify licensure through License Lookup at Board's website

New Staff in Enforcement Division

- Paul Dalby hired to supervise pharmacists inspectors and oversee inspection program for Pharmacy, Funeral, and Veterinary Medicine
- Timothy Reilly hired as 5th pharmacist inspector

Department of Health Professions

- Board of Pharmacy website:
  www.dhp.virginia.gov/pharmacy

- Email : pharmbd@dhp.virginia.gov

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